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Date: June 11, 2008 Name: Sheryl L. Hutchings Signature: Sheryl L Hutchings

PATENT
Case No. 8627/096 (PA-5245-RFB)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	)
	) Art Unit: 3733
Fred T. Parker	)
	) Examiner: Anuradha Ramana
Serial No.: 09/815,567	)
	) Confirmation Number: 6497
Filed: March 23, 2001	)
	)
For: INTRODUCER SHEATH	)

BRIEF OF APPELLANT

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This appeal is taken from the decision of the Examiner dated February 1, 2008, finally rejecting claims 1-13, 15-20, 22 and 23 of the present application.

Appellant timely filed his Notice of Appeal to the final rejections on March 13, 2008. A Pre-Appeal Brief Request for Review was also submitted at that time. In the Notice of Panel Decision from Pre-Appeal Brief Review, mailed May 13, 2008, the claim rejections were maintained.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is the Assignee of the application, Cook Incorporated.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellant or Appellant's legal representatives which will directly affect or be directly affected by or have a bearing on the Board's decision in the instant matter.

III. STATUS OF CLAIMS

Claims 1-13, 15-20, 22 and 23 were presented for examination.

Claims 1-13, 15-20, 22 and 23 stand finally rejected and are appealed herein.

Claims 14 and 21 have been canceled.

IV. STATUS OF AMENDMENTS

No amendments to the claims were presented subsequent to the final rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to a flexible, kink-resistant, introducer sheath. The sheath has an outer tubular member having a greater flexibility at the distal end portion than at a proximal portion.

Introducer sheaths are well known for percutaneous vascular access. Such sheaths can be of thin-walled construction, and are prone to kinking as they pass through the body vessel. When a sheath kinks in a body vessel, the sheath is unusable and must be removed from the patient. Increasing the thickness of the sheath only minimally improves the level of kink resistance, while at the same time undesirably enlarging the entry hole.

A prior art introducer sheath with improved kink resistance was disclosed by the present inventor in U.S. Patent No. 5,380,304: Generally speaking, this prior art sheath comprises a coil having a plurality of turns fitted around an inner lubricious tube. An outer tube is connected to the inner tube through the spacings of the coil turns. The outer tube comprises a heat-formable polyamide material, such as nylon, for connecting with an outer surface of the inner tube, between the coil turns. The patent also discloses a sheath distal tip portion of the same durometer, or harder,

than the durometer of the outer tube. The distal tip portion is thermally bonded to a tapered distal end of the outer tube. This prior art sheath is illustrated at Figs. 1 and 2 of the present application, and is discussed, e.g., at page 2, lines 1-18, and at page 3, line 26 to page 4, line 29 of the application.

The distal tip member in the prior art structure is provided to facilitate entry into the percutaneous access site. Although a sheath having a high durometer tip is effective for facilitating entry into many percutaneous access sites, such tips are not desirable in all instances. For example, when a tortuous path through the body must be traversed, or when highly sensitive treatment sites must be accessed, a softer, more flexible distal tip portion may be desired.

The introducer sheath of the present invention includes an inner lubricious tube 12, and a wire coil 14. The wire coil comprises a plurality of uniformly spaced coil turns wound around the inner tube, which turns are free from being interwoven with another coil turn (Figs. 3, 4). A first, proximal length 20 of outer tubing of a relatively high durometer material extends along most of the length of the coil-wound inner tube. A second, distal length 22 of outer tubing having a lower (e.g. softer) durometer than the first length of outer tubing is placed over the remainder of the length of the inner tube. Both the first and second lengths of outer tubing can be melted to flow between the spacings of the coil wire to bond to the outer surface of the inner tube, and to thermally bond to each other at the abutment location. Preferably, the distal end of the second outer tubing length is tapered, and the sheath is fabricated having a flexible distal tip portion. Page 5, line 1 to page 6, line 15. The inventive introducer sheath is particularly beneficial in applications involving tortuous bodily passageways, such as renal and other arterial applications, and in uses where an atraumatic flexible kink-resistant distal tip portion is desired. Page 3, lines 9-12.

<u>VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL</u>

1. Claims 1-2, 4-5, 10-13, 15-20, 22 and 23 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187).

2. Claim 3 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. in view of Park et al. as applied to claim 1, and further in view of Parker (US 5,380,304).

3. Claims 6-9 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. in view of Park et al., further in view of Ju et al (US 5,599,325).

4. Claims 1-13, 15-20 and 22 have been rejected under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement.

5. Claims 1-13, 15-20 and 22 have been rejected under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VII. ARGUMENT

Issue 1.

Claims 1-2, 4-5, 10-13, 15-20, 22 and 23 are not unpatentable under 35 U.S.C. §103(a) over Horrigan et al. in view of Park et al.

Horrigan was cited by the Examiner as disclosing a sheath having certain features in common with the claimed invention, including a lubricious inner tube 40, and first and second outer tubes 15, 20, wherein the second (distal) outer tube is made of a softer material than the first outer tube. The Examiner conceded that Horrigan did not disclose the use of a coil as a reinforcement means, but rather, disclosed a wire braid as a reinforcement means. Park was cited for disclosing a catheter section having a wire coil. According to the Examiner, it would have been obvious to have substituted a wire coil as disclosed in Park for the wire braid of Horrigan.

The present invention is directed to a flexible, kink resistant introducer sheath. A sheath that is flexible and kink resistant can be more easily advanced through tortuous body passageways, and directed to target sites deep within the vasculature of a patient. As a sheath is advanced through tortuous body passageways, it is desirable that the sheath maintain as much of its generally circular cross-section through as large a bending angle as possible. As long as the generally

circular cross-section of the sheath remains at least substantially intact, the physician can deliver the largest possible medical interventional device, such as a stent, through the sheath for deployment at the target site. If a sheath kinks as it traverses these passageways, the cross-section collapses (in the nature of a bent plastic straw) and the sheath becomes un-useable. In this event, the kinked sheath must be removed, and replaced with a new sheath. This adds unnecessary cost to the procedure, and increases the level of difficulty of the procedure. It also increases the amount of time required to complete the procedure, if it can be completed at all.

Providing a coil-reinforced sheath enables the physician to negotiate tight bends in bodily passageways, such as the vasculature, that often cannot be negotiated with sheaths that are not equipped with this type of reinforcement. As a result, an interventional device that has an outer diameter nearly as large as the inner diameter of a sheath can be passed through the sheath even after the sheath has been bent through a wide bending angle. A wide bending angle of the type that can be achieved with a sheath having a coil reinforcement cannot typically be achieved with a sheath having a braid reinforcement.

Appellant disputes the Examiner's contention that modifying a sheath having a braid reinforcement, such as the Horrigan sheath, by substituting a wire coil for the braid was an obvious modification. During prosecution of this application, Appellant provided numerous declarations in support of his contention that this substitution was not obvious, and indeed, that a sheath having a coil reinforcement could be introduced, without kinking, into body passageways with a much greater bending angle than was possible with a sheath having a braid reinforcement.

In order to illustrate the different bending capabilities of sheaths equipped with a braid reinforcement, and a coil reinforcement, respectively, Appellant presented, *inter alia*, the Declaration of Sathya Kaliyamoorthy, Ph.D. Dr. Kaliyamoorthy's Declaration was provided to report and explain the conclusions arrived at following a Finite Element Analysis ("FEA") computer simulation test that he carried out. The Kaliyamoorthy Declaration was appended to Applicant's response of April 24, 2007. In this FEA simulation, Dr. Kaliyamoorthy compared the kink resistance of a sheath representative of the braided sheath taught in

Horrigan, with the kink resistance of a sheath *otherwise similar to the Horrigan sheath* but having a coil reinforcement instead of the braid reinforcement (Kaliyamoorthy Declaration, paragraph 5). The aim of the test was to establish whether a sheath having a coil reinforcement exhibited greater kink resistance than an otherwise similar sheath having a braid reinforcement.

Dr. Kaliyamoorthy stated the following in his declaration:

> 5. I was asked by Cook Incorporated, ("Cook") of Bloomington, Indiana, to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), and U.S. Patent No. 5,792,124 to Horrigan, et al., ("Horrigan"). The Horrigan patent was represented to me as being the closest prior art reference cited by the Patent Examiner during prosecution of the '567 application. I was asked to design a computer simulation utilizing Finite Element Analysis ("FEA") to compare the kink resistance of a sheath constructed in accordance with the teachings of the Horrigan patent, to the kink resistance of a sheath otherwise similar to the sheath taught in Horrigan but having a coil reinforcement instead of the braid reinforcement disclosed in Horrigan.
>
> 6. The basic computer simulation model that I constructed for the FEA analysis was designed to be representative of a sheath taught in Horrigan. Another model was designed to be representative of the sheath taught in Horrigan, except that a coil reinforcement was substituted for the braid reinforcement of the Horrigan sheath. Whenever possible, the dimensions of the sheaths utilized for purposes of our FEA analysis were selected to be within a range specifically recited in Horrigan. When a specific dimension for a feature was not explicitly recited in Horrigan, a dimension was selected that was believed appropriate in view of the overall teachings of the Horrigan reference. The specific dimensions used in the FEA were also consistent with physical prototypes used for testing.

As further stated by Dr. Kaliyamoorthy, according to his FEA computer simulations, the braid-reinforced sheath representative of the Horrigan sheath quickly began to lose its normalized diameter upon bending, and kinked at a relatively small bending angle of about 21 degrees. At this angle, the normalized stent diameter was reduced to about 0.6, or in other words, the circularity of the sheath was about 60% of normal diameter. Upon further bending, the braid-

reinforced sheath lost its entire diameter at a bending angle of about 47 degrees. (Kaliyamoorthy Declaration, paragraph 10.)

On the other hand, at the same bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This coil-reinforced sheath maintained a circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees. Thus, it was demonstrated that the coil-reinforced sheath was able to be bent to a much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a circularity greater than 70% of its original diameter. (Kaliyamoorthy Declaration, paragraphs 11, 12.) This distinction is perhaps best observed when viewing Exhibit B, attached to the Kaliyamoorthy Declaration.

To place these findings in a real-world context, Dr, Kaliyamoorthy established that a stent or other interventional medical device having a diameter approaching that of the normalized diameter of the bent sheath can be passed through the coil-reinforced sheath until the sheath is bent to an angle of 67 degrees. On the other hand, with a braid-reinforced sheath, the sheath loses much of its normalized stent diameter at a bending angle of only 21 degrees, and loses its entire diameter at 47 degrees. This sheath would have only limited utility for passage of a small diameter stent therethrough once it reaches a bending angle of 21 degrees, and would have no utility for such passage at a bending angle of 47 degrees. Clearly, the FEA test showed that the sheath having a coil reinforcement has utility at bending angles at which the sheath having a braid reinforcement would be unusable. This difference can be critical when the physician is attempting to position a medical interventional device, such as a stent, at a branched or otherwise tortuous passageway of the body. In many such cases, a placement utilizing a coil-reinforced introducer sheath would be successful, while an attempted placement with a braid-reinforced sheath would fail.

The primary Horrigan reference teaches a braided guiding catheter for use in PTCA. According to the patent specification, it is an important characteristic of such catheters that they have sufficient stiffness to be pushed through vessels, as well as sufficient rigidity to provide a high degree of torsional control. Col. 1, lines

15-21. In order to be able to achieve these objectives, Horrigan utilized a braid-reinforced sheath, because such sheaths are generally considered superior to a coil-reinforced sheath when properties such as stiffness and pushability (as opposed to kink resistance) are of paramount concern. (See, Declaration of Thomas A. Osborne, appended to Applicant's response of April 29, 2004, paragraph 7). The Horrigan reference neither teaches nor suggests an optimal manner of traversing a tortuous passageway in a manner to avoid kinking. In fact, by his use of a braided reinforcement, Horrigan teaches away from the advantages with regard to kink resistance that may be achieved when a coil reinforcement is used.

The secondary Park reference teaches a complex solution to the problem of providing access to a target site through increasingly small vessels. The solution to this problem advocated by Park differs considerably from the teachings of the present invention. Park utilizes a catheter having a distal tip section that includes a forming member, such as a woven braid or a coil, formed of a super-elastic material. The forming member is placed in the catheter section and treated in such a way that it has a "second" shape in its equilibrium condition. The forming member is held in a "first", non-equilibrium shape by the presence of an outer polymeric layer. Upon the application of heat to the catheter section in the first shape, the outer restraining layer softens, such that the forming member, and therefore the catheter tip, bends or otherwise assumes the second shape. See, e.g., Col. 8, lines 33-43. Also, compare Figs. 1A and 1B in the Park patent. According to the patent, even though the use of a braid reinforcement may improve the ability of the catheter to transmit torque, at times braiding alone is insufficient. In such cases, "[p]roviding a small amount of shape to the distal section of the catheter can mean the difference between a successful procedure and one that is not as successful." Col. 9, lines 14-17.

Thus, Park acknowledges that although the use of a braid improves the ability to transmit torque (a conclusion that is well known to those skilled in the art, and was discussed at paragraph 7 of the Osborne Declaration), the use of the super-elastic forming member as the braid provides advantages not always attainable with a conventional braid. According to Park, the catheter disclosed therein is superior in

certain instances when compared to a catheter having a conventional reinforcing member.

At page 7 of the final Office Action mailed February 1, 2008, the Examiner stated that it would have been obvious for a person of ordinary skill in the art to have used reinforcement in the form of a flat wire coil instead of a "braided wire coil" as taught in Horrigan because Park et al "teaches the use of a braided wire coil or a flat wire coil as types of reinforcement utilized in the same field of intravascular devices."

Appellant disputes that any such conclusion may be reached upon review of the cited references. Appellant respectfully submits that in evaluating the scope of the Park disclosure, one must carefully examine the teachings therein. When properly construed, it is apparent that Park makes no claim of equivalence, or exchangeability, among different types of reinforcements. Nor does he suggest that such substitution is possible or desirable, or even suggest any instances when such a substitution should be made. Rather, the teaching in Park is much more narrowly directed to a very specific catheter construction having a distal tip section that is formable (e.g., bendable) from a first, constrained, shape to a second, equilibrium, shape.

The benefits of this very specific construction of the distal tip may be achieved when applied to catheters having a braid reinforcement, as well as those having a coil reinforcement. However, in each case, the proper comparison must be to the specific type of reinforcement (such as a braid) with, and without, the formable capabilities of the distal tip. The fact that the asserted benefits of Park may also be achieved with different types of reinforcement (as alleged by Park) cannot be used to infer any equivalence, or interchangeability, between different types of reinforcement, such as a braid and a coil. Any suggestion of this goes well beyond the disclosure of Park.

There is no teaching or suggestion of equivalence or interchangeability in general between such reinforcements, nor is the patent even concerned with making such a comparison. It is clear that Park does not discuss any benefits in kink resistance that may be achieved when a coil reinforcement is utilized instead of a

braid, or vice versa. In fact, Park provides no reasons why one skilled in the art would ever want to use a coil reinforcement instead of a braid. In this vein, the teaching of Park is consistent with Horrigan, which also provides no reasons why an artisan would ever want to use a coil reinforcement.

Although Park indicates that his device exhibits (among numerous other cited properties) a certain amount of kink resistance in some circumstances (Col. 2, lines 40-44), this teaching must be read in the context of the invention that he espouses, namely a catheter having a self-formable tip. In view of Park's stated preference for a braid in his preferred embodiments, one skilled in the art would be led away from the present invention, by erroneously assuming that a braided reinforcement provides better kink resistance than a coil reinforcement. This contention has already been rebutted in the Kaliyamoorthy and Osborne Declarations. Simply put, Appellant submits that one skilled in the art would not reach the conclusions espoused by the Examiner concerning the alleged equivalency and/or interchangeability between a braid and a coil upon a review of the Park patent.

Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13, 15-20, 22 and 23 are not obvious in view of the cited combination.

Issues 2 and 3.

Claim 3 is not unpatentable under 35 U.S.C. §103(a) over Horrigan et al. in view of Park et al. as applied to claim 1, and further in view of Parker (US 5,380,304). Claims 6-9 are not unpatentable under 35 U.S.C. §103(a) as being obvious over Horrigan et al. in view of Park et al., further in view of Ju (US 5,599,325).

As indicated above, Issue 2 relates specifically to dependent claim 3, and Issue 3 relates specifically to dependent claims 6-9. For purposes of this appeal, these issues may be dealt with together.

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface, and Ju was cited for its teaching of an outer

sheath tube made from a blend of a polymer and a radiopaque filler. Applicant respectfully submits that these references do not overcome the shortcomings recited above with regard to the rejection of claim 1. Claims 3 and 6-9 are dependent, directly or indirectly, from claim 1. Therefore, these claims include all of the limitations of claim 1, and are allowable for at least the same reasons that claim 1 is allowable.

Issues 4 and 5.

Claims 1-13, 15-20 and 22 are not unpatentable under 35 U.S.C. §112, 1st paragraph, as failing to comply with the written description requirement. Claims 1-13, 15-20 and 22 are not unpatentable under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Issues 4 and 5 relate to formal matters, and may be dealt with together. In the final Office Action of February 1, 2008, the Examiner rejected claims 1-13, 15-20 and 22 under 35 USC 112, 1st and 2nd paragraphs. Specifically, the Examiner stated that the term "uniformly spaced coil turns" was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention (1st paragraph), and that the claims are indefinite as a result of this terminology (2nd paragraph).

In response, Appellant states that this terminology was added to independent claims 1 and 22 in Applicant's Response of October 18, 2007, in response to the Examiner's contention in the previous action that: "Applicant's arguments are not directed to claim limitations since claim 1 does not recite that the spacing between the turns is uniform." Appellant had not previously included this term in the claims because it was not believed necessary to distinguish the cited art. However, in order to advance prosecution, the term was added to the claims in Applicant's Response to address the concerns raised by the Examiner.

In the Response, Applicant stated that support for the amendment was provided at Figs. 2-4 of the application, which illustrate a coil having uniformly spaced turns. Citation was also made to Col. 4, lines 9-11 ("Coil 23 comprises a

plurality of flat wire turns, for example, 27-31, with uniform spacing including equal width spaces 32-35 therebetween."), and additionally, to Figs. 2-4 of Applicant's earlier U.S. Patent No. 5,380,304. Figs. 2-4 of the '304 patent are essentially the same as Figs. 2-4 of the instant application.

Appellant disputes the Examiner's contention that this terminology was not described in such a way as to reasonably convey to the skilled artisan that the inventions had possession of the claimed subject matter, and that the claims are indefinite as a result of this terminology. To the contrary, Appellant respectfully submits that in view of the text and figures of the '304 patent, one skilled in the art would have absolutely no difficulty understanding the meaning of this terminology in the present claims.

CONCLUSION

For the foregoing reasons, Appellant respectfully submits that the grounds for the Examiner's rejections of claims 1-13, 15-20, 22 and 23 are not well taken, and should be reversed by this Board.

Respectfully submitted,

Lawrence A. Steward
Attorney for Appellant
Attorney Reg. No. 32,309

BRINKS HOFER GILSON & LIONE
One Indiana Square, Suite 1600
Indianapolis, IN 46204
(317) 636-0886

VIII. CLAIMS APPENDIX

1. A flexible, kink-resistant introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of uniformly spaced coil turns;

a first outer tube disposed around said wire coil and said inner tube therewithin to a first outer tube distal end spaced proximally from said wire coil distal end such that a distal end portion of said wire coil extends distally therebeyond; and

at least a second outer tube disposed around said wire coil and said inner tube therewithin extending distally from said first outer tube distal end and covering said distal end portion of said wire coil and extending slightly beyond said distal end of said inner tube,

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a substantially softer durometer than said material of said first outer tube.

2. The introducer sheath according to claim 1, wherein said first and second outer tubes are bonded to each other and to said wire coil, and to said inner tube between windings of said wire coil.

3. The introducer sheath according to claim 2, wherein an outwardly facing surface of said inner tube has been roughened to enhance bonding thereto of said first and second outer tubes.

4. The introducer sheath according to claim 2, wherein said bonding is heat bonding.

5. The introducer sheath according to claim 1, wherein a radiopaque marker band is affixed to said wire coil distal end within said second outer tube.

6. The introducer sheath according to claim 1, wherein said second outer tube is polymeric and contains radiopaque filler.

7. The intravascular sheath according to claim 6, wherein said second outer tube contains between about 20% and 85% by weight of radiopaque filler particles.

8. The introducer sheath according to claim 6, wherein said second outer tube contains about 80% by weight of radiopaque filler particles.

9. The introducer sheath according to claim 1, wherein said first outer tube is substantially free of radiopaque filler.

10. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of at least 5 D lower than that of the material of the first outer tube.

11. The introducer sheath according to claim 10, wherein said first outer tube comprises a material having a durometer of about 56D to 58D.

12. The introducer sheath according to claim 1, wherein said second outer tube comprises a material having a durometer of between about 10D and 75D.

13. The introducer sheath according to claim 12, wherein said second outer tube comprises a material having a durometer of about 39D.

14. (canceled)

15. The introducer sheath according to claim 1, wherein said wire coil comprises flat wire.

16. The introducer sheath according to claim 1, wherein a distal tip region of the sheath is arcuate.

17. The introducer sheath according to claim 16, wherein said arcuate distal tip region has a length of about 1 cm or more.

18. The introducer sheath according to claim 16, wherein said arcuate distal tip region extends about an angle of about 90°.

19. The introducer sheath according to claim 1, wherein said wire coil extends for a length of about five millimeters beyond said distal end of said first outer tube.

20. The introducer sheath according to claim 1, wherein said inner tube is unitarily formed.

21. (canceled)

22. A flexible, kink resistant introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to a wire coil distal end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of uniformly spaced coil turns, each coil turn being free from crossing by another coil turn;

a first outer tube disposed around said wire coil and said inner tube to a first outer tube distal end spaced proximally from said wire coil distal end; and

a second outer tube extending distally from said first outer tube distal end and disposed around and covering said distal end portion of said wire coil and said inner tube and extending slightly therebeyond;

said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material of a durometer softer than the durometer of the first outer tube.

23. An introducer sheath comprising:

an inner tube extending to a distal end;

a wire coil wound around said inner tube extending to an end spaced proximally from said inner tube distal end, said wire coil comprising a plurality of coil turns, each turn being free from being interwoven with another coil turn;

a first outer tube disposed around said wire coil and said inner tube to a first outer tube distal end spaced proximally from said wire coil distal end; and

at least a second outer tube disposed around said wire coil and said inner tube extending distally from said first outer tube distal end and covering said distal end portion of said wire coil, said first outer tube being of a material having a relatively hard durometer, and said second outer tube being of a material having a softer durometer than said material of said first outer tube.

IX. EVIDENCE APPENDIX

Appended herein are two Rule 1.132 declarations cited in this Brief, and relied upon by Appellant.

The appended Declaration of Thomas A. Osborne was attached to Applicant's Response filed on April 29, 2004, and entered into the record of this case on May 3, 2004. This Declaration was referenced in the Office Action of June 29, 2004.

The appended Declaration of Sathya Kaliyamoorthy was attached to Applicant's Response filed on April 24, 2007, and entered into the record of this case on April 24, 2007. This Declaration was referenced in the Office Action of September 11, 2007.

X. RELATED PROCEEDINGS APPENDIX

None.

PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Fred T. Parker Serial No.: 09/815,567 Filed: March 23, 2001 For: INTRODUCER SHEATH	))))))))))	Art Unit: 3751 Examiner: A. Ramana

RULE 1.132 DECLARATION

I, Thomas A. Osborne, declare as follows:

1. I am employed by Cook Incorporated ("Cook") of Bloomington, Indiana, the assignee of the above-referenced United States Patent Application Serial No. 09/815,567 ("the '567 application").

2. I have been employed by Cook in various capacities since 1964. My present title is Senior Vice President of Intellectual Property, Engineering, Training and Development. In the course of my employment, I oversee new product development and production, and new invention disclosures. The areas that I oversee include the development and production of introducer sheaths. At times, I also formulate new invention disclosures related to introducer sheaths.

3. I am an inventor on 30 issued U.S. patents, and numerous additional foreign patents. I am also an inventor on numerous U.S. and foreign pending patent applications.

4 I have reviewed the '567 application, the Office Actions received from the United Stated Patent and Trademark Office ("PTO") and the responses filed on behalf of the applicant, as well as the references cited by the Patent Examiner in support of the rejection of the claims.

5. In Paper No. 17, mailed September 24, 2003, the Examiner stated at page 6: "Appellant's attention is directed to Park et al. who teach the equivalence of a braid or coil for reinforcement of an intravascular device for use in an environment of increasingly small diameters for resistance to kinking (col. 1, lines 9-11 and lines 29-52 and col. 8. lines 29-36)."

6. I disagree with the Examiner's premise that a braid and coil are equivalent for resistance to kinking, and disagree that such a conclusion can be reached from the teaching of the Park patent. It is true that wire braids and wire coils may be considered interchangeable in some instances. However, the Examiner's comments quoted above are much too broad, and do not take into account those instances where the differences between a coil reinforcement and a braid reinforcement can be very significant.

7. With regard to certain properties of a sheath, such as its burst resistance or its crush resistance, the use of a coil reinforcement or a braid reinforcement may be considered generally interchangeable. With regard to certain other properties of a sheath, such as stiffness, pushability or torqueability, a braid reinforcement is superior to a coil reinforcement. On the other hand, when it is desired to maximize the kink resistance of a sheath, a coil reinforcement is superior to a braid reinforcement.

8. The ability to resist kinking is a key factor in the usefulness of an introducer sheath. Such sheaths are frequently used to access tortuous passageways in the vasculature of a patient for the deployment of an interventional device, such as a stent or an angioplasty balloon, that has an outer diameter that is close to the inner diameter of the sheath. During a deployment, a sheath must often traverse a bend of 90° or more. On example of such a bend that must be traversed in an interventional procedure is the bend from the aorta to the renal arteries. This bend is about 90°, and must occur in a radius of about 15 mm. The lumen of the sheath must maintain its round cross-section so that the interventional device can pass through the lumen. Even partial kinking or ovality can prevent such passage, and render the sheath useless.

9. A coil forces the cross section of the inner lumen of a coil-reinforced sheath to remain round by causing the stresses on a bended portion to stretch the material on the outside of the bend and compress the material on the inside of the bend. When a sheath having a braid reinforcement bends, the braid does not allow expansion on the outside of a

curve or compression on the inside of a curve. Since the wall of the braid-reinforced sheath is longitudinally rigid, the stresses produced in a bend force the wall on the outside of the bend and the wall on the inside of the bend toward the central axis of the sheath, thus forcing the lumen to become oval and eventually kink.

10. In order to demonstrate the differences in kink resistance between a coil-reinforced sheath and a braid-reinforced sheath, I performed bending tests on two 10 French (3.3 mm) sheaths. Each tube included an inner liner formed of PTFE and an outer jacket formed of PEBAX. The wall thickness of the tubes was about 0.25 mm. One of the tubes included a stainless steel wire coil reinforcement embedded in the outer jacket, and the other tube included a stainless steel wire braid reinforcement embedded in the outer jacket. Other than the type of reinforcement, the tubes were otherwise identical.

11. During my testing, I bent each tube an equivalent distance to obtain a curve, and photographed the curved portion under a microscope. The photographs are attached hereto as Exhibits A and B. The bends are comparable to bends that would be encountered when attempting to place a stent in the vasculature of a patient.

12. Exhibit A shows the bending of the coil-reinforced tube. As may be observed, the coils spread apart on the outside of the bend, while they move closer on the inside of the bend. This allows the polymer that encases the coil to stretch between the coils on the outside of the curve. Correspondingly, the polymer compresses, or bunches up, on the inside of the curve. This unique property of a coil when compared to a braid allows one to take advantage of polymers with elastic properties, and to avoid kinking.

13. Exhibit B shows the bending of the braid-reinforced tube. As may be observed, the braid does not allow expansion on the outside of the curve or compression on the inside of the curve. As a result, the tube kinks after only slight bending. If one were to use a more elastic material for this tube, the tube would still kink, although it would just take less force to get it to kink.

14. When it is desired to maximize the kink resistance of a sheath, a coil-reinforced sheath is superior to a braid-reinforced sheath. The use of a tube having a braided reinforcement does not improve the ability of the tube to withstand kinking, and in fact, may enhance kinking as shown in Exhibit B. When a sheath has kinked in this manner, the interventional device cannot be passed through the sheath, and the operation has failed.

15. In addition to the foregoing, there are other advantages to the use of a coil reinforcement when compared to a braid reinforcement. When an introducer sheath is to be inserted through tortuous passageways in the vasculature of a patient, it is important that the cross-sectional diameter be maintained as small as possible to accomplish the purposes of the sheath. The cross-sectional diameter of a sheath having a braid reinforcement is greater than the cross-section of a sheath having a coil reinforcement, all other things being equal. This is true whether a flat wire coil is compared to a flat wire braid, or whether a round wire coil is compared to a round wire braid. Another advantage is that an introducer sheath having a coil reinforcement is easier and less costly to manufacture than a sheath having a braid reinforcement. This is due to the fact that when a braid reinforcement is utilized, the ends of the braid must be fused or otherwise adhered to the inner liner of the sheath. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying if not properly fused or adhered. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil, or its ends, is required.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on April 28, 2004, at Bloomington, Indiana.

Thomas A. Osborne

Thomas A. Osborne

Exhibit A

flexor1.jpg (640x480x24b jpeg)

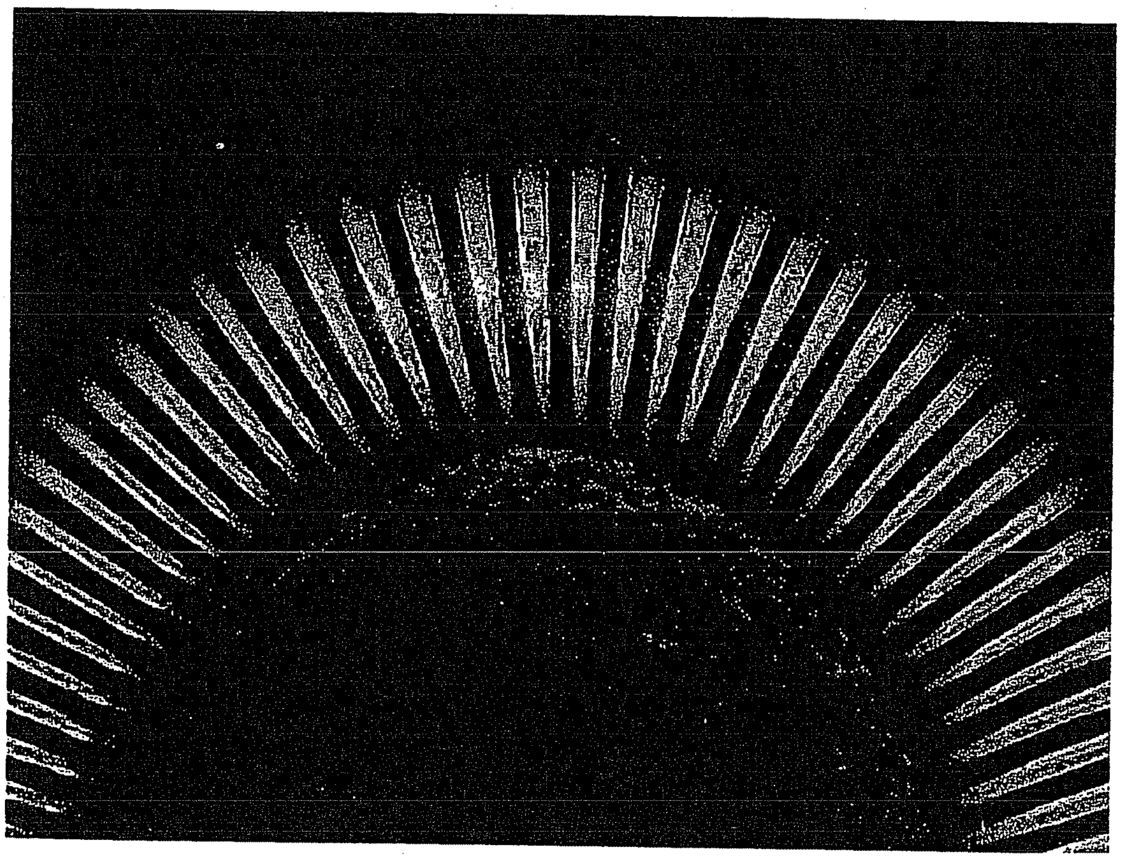
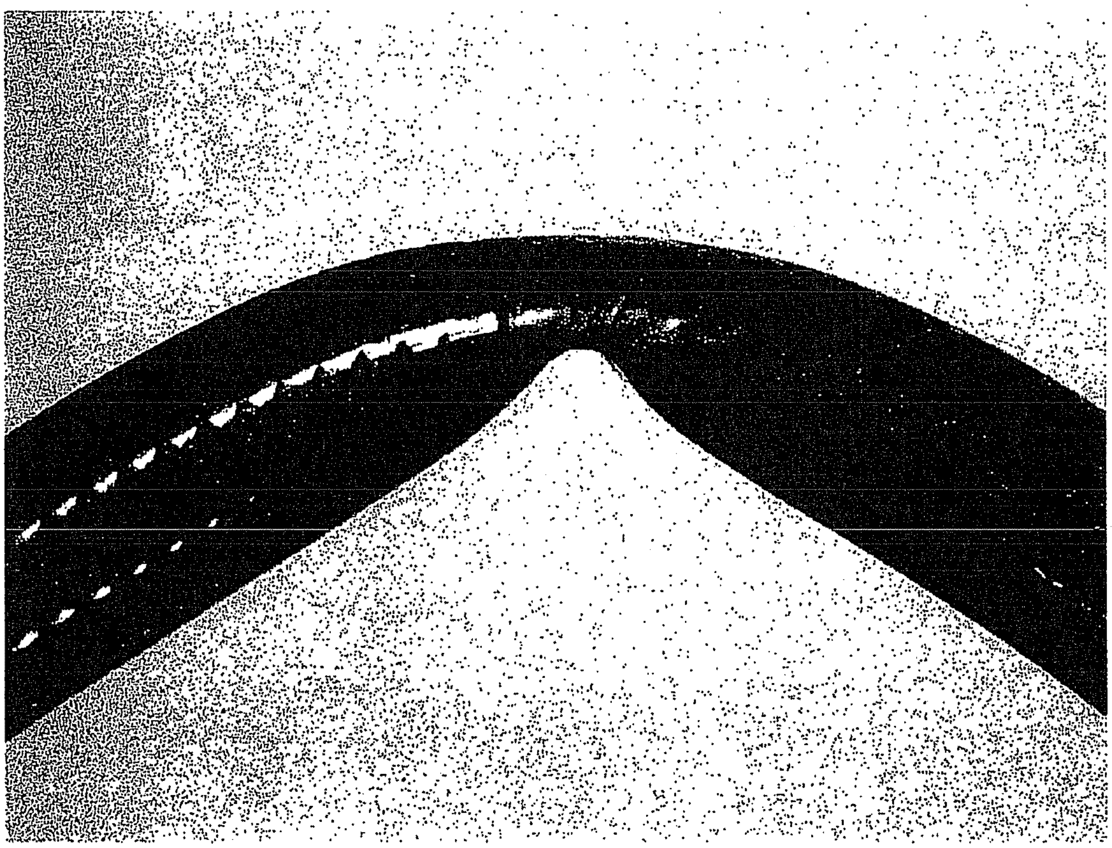


Exhibit B

lumaxl.tif (640x480x24b tiff)



PATENT

Case No. 8627/096

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	Art Unit: 3751
Fred T. Parker	)	
	)	Examiner: A. Ramana
Serial No.: 09/815,567	)	
	)	
Filed: March 23, 2001	)	
	)	
For: INTRODUCER SHEATH	)	
	)	

RULE 1.132 DECLARATION

I, Sathya Kaliyamoorthy, declare as follows:

1. I am over 18 years of age and competent to make this Declaration.

2. I graduated from the Case Western Reserve University in 2003 with a Ph.D. in Mechanical Engineering.

3. Since 2003, I have been employed by ABAQUS, Inc., of West Lafayette, Indiana. The primary business of ABAQUS is sales, support, and for-fee consulting using the ABAQUS computer program. ABAQUS performs Finite Element Analysis ("FEA"). FEA allows engineers to simulate the physical behavior of engineered products using a computer. FEA further allows these engineers to minimize the number of physical prototype tests performed during development of their products. FEA further allows engineers to gain deeper understanding into the physics of their products than can be gained by physical test alone. The ABAQUS program is commonly used in many industries. Particularly in the medical industry, ABAQUS is commonly used to simulate stents, catheters, and other interventional medical devices.

4. Prior to joining ABAQUS, I was employed by the Cleveland Clinic Foundation for a period of one year as a Research Scholar.

5. I was asked by Cook Incorporated, ("Cook") of Bloomington, Indiana, to examine Cook's United States Patent Application Serial No. 09/815,567 ("the '567 application"), and U.S. Patent No. 5,792,124 to Horrigan, et al., ("Horrigan"). The Horrigan patent was represented to me as being the closest prior art reference cited by the Patent Examiner during prosecution of the '567 application. I was asked to design a computer simulation utilizing Finite Element Analysis ("FEA") to compare the kink resistance of a sheath constructed in accordance with the teachings of the Horrigan patent, to the kink resistance of a sheath otherwise similar to the sheath taught in Horrigan but having a coil reinforcement instead of the braid reinforcement disclosed in Horrigan.

6. The basic computer simulation model that I constructed for the FEA analysis was designed to be representative of a sheath taught in Horrigan. Another model was designed to be representative of the sheath taught in Horrigan, except that a coil reinforcement was substituted for the braid reinforcement of the Horrigan sheath. Whenever possible, the dimensions of the sheaths utilized for purposes of our FEA analysis were selected to be within a range specifically recited in Horrigan. When a specific dimension for a feature was not explicitly recited in Horrigan, a dimension was selected that was believed appropriate in view of the overall teachings of the Horrigan reference. The specific dimensions used in FEA were also consistent with physical prototypes used for testing.

7. The sheath model based upon the Horrigan teaching was constructed according to the Table attached hereto as Exhibit A. The sheath model was designed to have two layers of polymeric material. The inner layer of the model was TEFLON®[1] (PTFE), and the outer layer of the model was PEBAX®[2] (a polyether block amide copolymer).

8. In the braid-reinforced model, the braid was represented by a 16-strand annealed stainless steel[3] braid. Each strand has a wire diameter of 0.0762 mm. The braid wires made an angle of 55 degrees with the longitudinal axis. In practice, this angle can allow all the strands of the braid to be accommodated while winding. In the coil-reinforced model, the coil was represented by a rectangular spring tempered cross section steel flat wire. The flat wire had a width vs. thickness of 0.3028 mm vs. 0.1016 mm. The dimension of the

[1] Horrigan, Col. 3, line 54
[2] Horrigan, Col. 4, line 34
[3] Horrigan, Col. 4, line 23

coil wire was selected such that the cross-sectional area of the coil wire is substantially equivalent to the cross-sectional area of the 16-strand braid. The coil made an angle of 86 degrees with the longitudinal axis. Since the coil has only one wire, this large angle can be practically possible to achieve while winding. In the FEA models, a commonly-used smeared equivalent modeling approach was used to include the additional stiffness of the braid- and coil-reinforcements in the two-layer tubular model. This smearing helps to efficiently build and run the FEA models.

9. Following the construction of the computer FEA models, each sheath model was "bent" to a progressively larger bending angle. This action was intended to simulate the behavior of the sheath when exposed to bending of a type that may be encountered as the sheath traverses a tortuous passageway in the vasculature. A graphical depiction of the results of the bending simulation is provided in Exhibit B, attached hereto.

10. According to Exhibit B, the braid-reinforced sheath quickly began to lose its normalized diameter upon bending, and kinked at a bending angle of about 21 degrees. At this bending angle, the normalized stent diameter was reduced to about 0.6 and the circularity was about 60% of normal diameter. Upon further bending the braid-reinforced sheath lost its entire diameter at a bending angle of about 47 degrees.

11. At the bending angle of 21 degrees, the coil-reinforced sheath maintained a circularity of about 96%. This sheath maintained a normalized diameter of over 0.7 and circularity in excess of 70% of the original diameter until reaching a bending angle of 67 degrees.

12. According to the parameters utilized in my simulation, the coil-reinforced sheath was able to be bent to a much greater angle (67 degrees vs. 21 degrees) than the braid-reinforced sheath, while maintaining a normalized stent diameter greater than 70% of its original diameter.

13. It is desirable to maintain as large a normalized stent diameter as possible, so that the largest possible stent or other medical device can be passed through the sheath for deployment at a target site in the vasculature. As evidenced by the data in Exhibit B, between a bending angle of 21 degrees and 67 degrees, a much larger stent could be passed through a sheath constructed according to the coil model when compared to a sheath constructed according to the braid model.

I declare under penalty of perjury pursuant to the laws of the United States of America that the foregoing is true and correct, and that this Declaration was executed by me on April 23, 2007, at West Lafayette, Indiana.

Sathya Kaliyamoorthy

Dimensions and Material Properties of the Sheath Designs

Variable	Data specified in Horrigan Patent	Picked value for FEA
Inner Layer (TEFLON)		
Elastic Modulus	-	460 MPa[1]
Inner Diameter	6Fr to 10Fr **Ref: Column 5; Line 1**	2.7178 mm (8 Fr)
Outer Diameter	Inner Diameter + 2*(Thickness =0.002 inch) **Ref: Column 4; Last but second line**	2.8194 mm
Outer Layer (PEBAX)		
Elastic Modulus	-	414 MPa[2]
Inner Diameter	Outer Diameter of Inner Layer	2.8194 mm
Outer Diameter	-	3.3020 mm
Braid Construction (16-strands)		
Wire Diameter	-	0.0762 mm
Angle with the longitudinal axis	-	55 Degrees
Elastic Modulus of the material of wire	Stainless Steel **Ref: Column 4; Second paragraph; Line 5**	200000 MPa
Coil Construction		
Width x Thickness	-	0.3048 mm x 0.1016 mm
Angle with the longitudinal axis	-	86 Degrees
Elastic Modulus of the material of coil	Stainless Steel	200000 MPa

[1]Typical value for TEFLON- Reference: DuPont **Teflon®** PTFE at Matweb
[2]Typical value for PEBAX- Reference: Arkema **Pebax®** 7033 at Matweb

EXHIBIT "A"

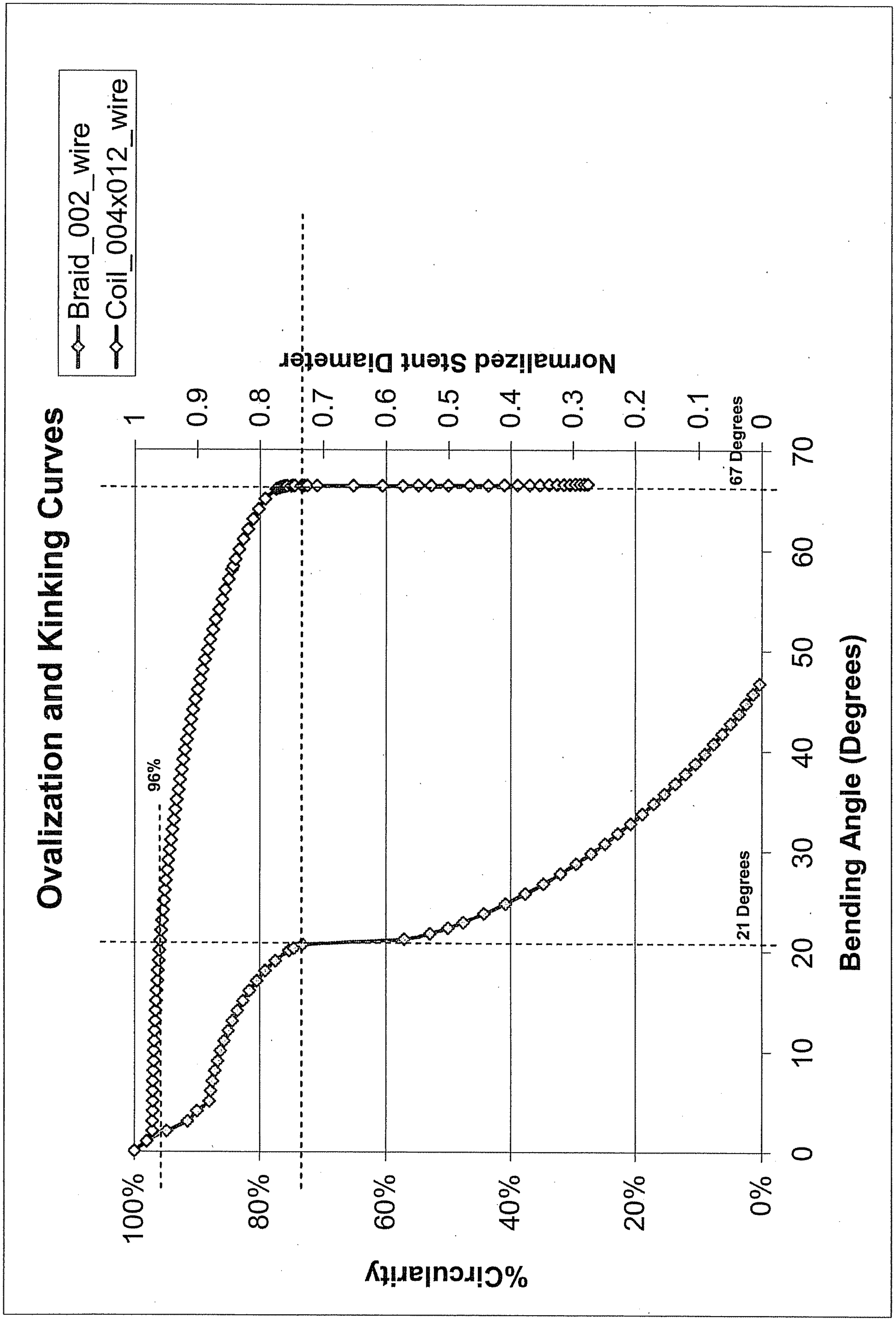

Ovalization and Kinking Curves
Braid_002_wire
Coil_004x012_wire
Normalized Stent Diameter
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
%Circularity
100%
80%
60%
40%
20%
0%
Bending Angle (Degrees)
0
10
20
30
40
50
60
70
96%
21 Degrees
67 Degrees

EXHIBIT "B"